

## PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY  
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 4 -32806A	<b>FOR FURTHER ACTION</b>		See Form PCT/IPEA/416
International application No. PCT/EP2004/003515	International filing date (day/month/year) 02.04.2004	Priority date (day/month/year) 04.04.2003	
International Patent Classification (IPC) or national classification and IPC A61K31/436, A61K31/167, A61K31/08, A61P17/00			
Applicant NOVARTIS AG et al.			

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
  - a.  *(sent to the applicant and to the International Bureau)* a total of sheets, as follows:
    - sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
    - sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
  - b.  *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:	
<input checked="" type="checkbox"/> Box No. I Basis of the opinion <input type="checkbox"/> Box No. II Priority <input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input checked="" type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input type="checkbox"/> Box No. VIII Certain observations on the international application	

Date of submission of the demand 23.10.2004	Date of completion of this report 25.02.2005
Name and mailing address of the International preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Tardi, C Telephone No. +49 89 2399-8180



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PCT/EP2004/003515

**Box No. I Basis of the report**

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
  - This report is based on translations from the original language into the following language, which is the language of a translation furnished for the purposes of:
    - international search (under Rules 12.3 and 23.1(b))
    - publication of the international application (under Rule 12.4)
    - international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

**Description, Pages**

1-10 as originally filed

**Claims, Numbers**

1-5 as originally filed

- a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3.  The amendments have resulted in the cancellation of:
  - the description, pages
  - the claims, Nos.
  - the drawings, sheets/figs
  - the sequence listing (*specify*):
  - any table(s) related to sequence listing (*specify*):
4.  This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
  - the description, pages
  - the claims, Nos.
  - the drawings, sheets/figs
  - the sequence listing (*specify*):
  - any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

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**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

the entire international application,

claims Nos. 3

because:

the said international application, or the said claims Nos. 3 regarding industrial applicability relate to the following subject matter which does not require an international preliminary examination (specify):

see separate sheet

the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

no international search report has been established for the said claims Nos. -

the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

has not been furnished

does not comply with the standard

the computer readable form

has not been furnished

does not comply with the standard

the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

See separate sheet for further details

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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

Novelty (N)	Yes: Claims	2
	No: Claims	1,3-5
Inventive step (IS)	Yes: Claims	
	No: Claims	1-5
Industrial applicability (IA)	Yes: Claims	1,2,4,5
	No: Claims	

2. Citations and explanations (Rule 70.7):

**see separate sheet**

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**Box No. VI Certain documents cited**

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1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

**see separate sheet**

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**Re Item III**

**Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

- 1) Claim 3 relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

- 1) Reference is made to the following documents:
  - D1: DATABASE WPI Section Ch, Week 200240 Derwent Publications Ltd., London, GB; Class B05, AN 2002-363575 XP002286184 & CN 1 338 290 A (HUANG J) 6 March 2002 (2002-03-06)
  - D2: DATABASE EPODOC EUROPEAN PATENT OFFICE, THE HAGUE, NL; 3 September 1997 (1997-09-03), XP002286182
  - D3: VIKTORINOVA M: "New antibiotic primycin in the treatment of pyoderma and acne" CESKO-SLOVENSKA DERMATOLOGIE 1998 CZECH REPUBLIC, 73(5), 1998, p.153-157, XP009032474 ISSN: 0009-0514
  - D4: WO 02/062353 A (WHARTON MARIE MADELINE) 15.08.2002
  - D5: US-A-5 064 815 (SCHREINER NEE KOVATS ENIKOE ET AL) 12.11.1991
  - D6: GB 766 245 A (LILLY CO ELI) 16 January 1957 (1957-01-16)
  - D7: DATABASE WPI Section Ch, Week 200318 Derwent Publications Ltd., London, GB; Class B05, AN 2003-181627 XP002286185 & RU 2 195 279 C1 (UNIV TULA) 27 December 2002 (2002-12-27)
  - D8: WO 99/24036 A (ORMEROD ANTHONY DAVID ; UNIV ABERDEEN (GB); WINFIELD ARTHUR (GB)) 20 May 1999
  - D9: US-A-6 120 792 (JUNI JACK E) 19 September 2000

Unless indicated otherwise, the relevant passages are those mentioned in the search report.

D1 discloses an ointment for treating burn comprising erythromycin and

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benzocaine.

D2 discloses a composition comprising spiramycin and lidocaine for the treatment of burn, scald, bed sore and knife wound.

D3 discloses a gel comprising primycin and lidocaine for the treatment of pyodermas and acne.

D4 describes a composition comprising an anaesthetic such as lidocaine and erythromycin for the treatment of skin ulcers.

D5 discloses a composition containing primycin and procaine for the treatment of mastitis.

D6 discloses a composition comprising erythromycin and a local anaesthetic such as procaine or benzocaine.

D7 describes a composition comprising novocaine and monomycin for the treatment of frostbite.

**2) Novelty (Art. 33(2) PCT)**

2.1 Combinations of a macrolide T-cell immunomodulator with a local anaesthetic, as well as their use for the treatment of a dermatological disease, have already been described in the prior art (see D1-D7).

Therefore the subject-matter of claims 1 and 3-5 is not new.

2.2 The subject-matter of claim 2 has not been disclosed in the available prior art.

**3) Inventive step (Art. 33(3) PCT)**

**3.1 Claim 2**

Claim 2 discloses a pharmaceutical composition comprising a combination of 33-epichloro-33-desoxyascomycin as a macrolide with lidocaine, polidocanol or prilocaine.

The use of both macrolides and local anaesthetics for the treatment of dermatological diseases is already known (see e.g. D8 and D9) and several compositions comprising a macrolide and a local anaesthetic for the treatment of a dermatological disease have already been described in the prior art (see D1-D4).

In the absence of any unexpected effect, 33-epichloro-33-desoxyascomycin and lidocaine, polidocanol or prilocaine thus appear to be mere alternatives that the skilled man could have chosen without the involvement of any inventive step.

Therefore the subject-matter of claim 2 does not fulfill the requirements of Art.

33(3) PCT.